DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 20-838/S-016
NDA 21-093/S-001

Astra Zeneca LP
Attention: Ms. Cindy M. Lancaster
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Lancaster:

Please refer to your supplemental new drug applications dated October 1 (NDA 20-838) and 25, 2001 (NDA 21-093), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand (candesartan cilexetil) Tablets, 4, 8, 16, and 32 mg (NDA 20-838) and Atacand HCT (candesartan cilexetil/hydrochlorothiazide) Tablets 16-12.5 and 32-12.5 mg (NDA 21-093).

We acknowledge receipt of your submission dated October 10, 2001.

These "Changes Being Effected" supplemental new drug applications provide for the following changes:

NDA 20-838/S-016

Under **ADVERSE REACTIONS**, the Post-Marketing Experience subsection now reads as follows:

The following have been very rarely reported in post-marketing experience:

Digestive: Abnormal hepatic function and hepatitis.

Hematologic: Neutropenia, leukopenia, and agranulocytosis.

Skin and Appendages Disorders: Pruritus and urticaria.

NDA 21-093/S-001

1. Under **ADVERSE REACTIONS**, *Candesartan Cilexetil*, a new Post-Marketing Experience subsection has been established that reads as follows:

   The following have been very rarely reported in post-marketing experience with candesartan cilexetil:

   Digestive: Abnormal hepatic function and hepatitis.

   Hematologic: Neutropenia, leukopenia, and agranulocytosis.

   Skin and Appendages Disorders: Pruritus and urticaria.

2. Under **HOW SUPPLIED**, the unit of use bottles of 30 have been deleted for the 16-12.5 and 32-12.5 mg tablet strengths.

We note that minor editorial changes have made to the package insert of both supplements.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package inserts included in your submissions of October 1 and 25, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Raymond Lipicky

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